

From: [Green, Tiffany](#)
To: llmathias@landolakes.com
Subject: Label Submission Due September 10th - NMFS Biological Opinion on Bromoxynil
Date: Thursday, September 2, 2021 11:12:00 AM
Attachments: [NMFS Biological Opinions Letter bromoxynil .pdf](#)

Dear Ms. Mathias,

Attached you'll find a letter regarding the National Marine Fisheries Service (NMFS) Biological Opinion on bromoxynil.

You are receiving this letter because your company holds registrations for bromoxynil products. Labels must be amended to be consistent with the NMFS Biological Opinion regarding the effects on 28 federally-listed endangered and threatened species of Pacific salmon and steelhead in Washington, Oregon and California.

The Biological Opinion for bromoxynil may be found on NMFS' website at:
<https://doi.org/10.25923/8agt-1p45>.

Your company must submit a cover letter, a completed Application for Registration (EPA form 8570-1) and copies of your amended product labels. For each label, submit two copies, a clean copy and an annotated copy with changes. In order for the application to be processed, include the following statement on the Application for Registration (EPA form 8570-1):

"I certify that this amendment satisfies the requirements of the NMFS Biological Opinion for bromoxynil, and no other changes have been made to the labeling of this product. I understand that it is a violation of 18 U.S.C. Section 1001 to willfully make any false statement to EPA. I further understand that if this amendment is found not to satisfy the requirements of the NMFS Biological Opinion, this product may be subject to regulatory action."

Within the required timeframe, submit the required documents to the Re-evaluation section of EPA's Pesticide Submission Portal (PSP). The PSP can be accessed through EPA's Central Data Exchange (CDX) using the following link: <https://cdx.epa.gov/>. Please be aware that the Agency is currently not accepting paper submissions because of COVID-19.

The deadline for receipt of your labels is **September 10, 2021**.

Based on the Biological Opinion, in the absence of this revised labeling, bromoxynil products will not have sufficient directions for use and/or precautionary statements to adequately protect federally-listed Pacific salmonid species. Therefore, failure to submit amended labels implementing the NMFS Biological Opinion for bromoxynil within the timeframe above may result in regulatory action.

Please let me know if you have any questions.

Best,
Tiffany

Tiffany Green
Chemical Review Manager

OSCPP/OPP/PRD/RMIB II

(703) 347-0314

green.tiffany@epa.gov



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

VIA E-MAIL, RETURN RECEIPT REQUESTED

July 12, 2021

Subject: Label changes necessary to comply with the June 25, 2021 National Marine Fisheries Services (NMFS) Biological Opinion on the effects of the following pesticides on Pacific salmonids: bromoxynil

Dear Sir or Madam:

You are receiving this letter because your company holds registrations for bromoxynil products. Labels must be amended to be consistent with the NMFS Biological Opinion regarding the effects on 28 federally-listed endangered and threatened species of Pacific salmon and steelhead in Washington, Oregon and California. The Biological Opinion requires reasonable and prudent measures (RPMs) to minimize the incidental take that could result from the use of these pesticides to individuals of listed species of salmon and steelhead or their critical habitats. The Biological Opinion for bromoxynil and prometryn may be found on NMFS' website at: <https://doi.org/10.25923/8agt-1p45>

Per the NMFS Biological Opinion for bromoxynil (see Chapter 18), the following label language must be added to the beginning of the "*Directions for Use*" section of all end-use product labels:

"Endangered Species Protection Requirements:

"It is a Federal offense to use any pesticide in a manner that results in an unauthorized "take" (e.g., kill or otherwise harm) of an endangered species and certain threatened species, under the Endangered Species Act section 9. When using this product, you must follow the measures contained in the Endangered Species Protection Bulletin for the area in which you are applying the product. You must obtain a Bulletin no earlier than six months before using this product. To obtain Bulletins, consult <http://www.epa.gov/espp/>, call 1-844-447-3813, or email ESPP@epa.gov. You must use the Bulletin valid for the month in which you will apply the product."

In addition, the following label language must be added to the "*Environmental Hazards*" section of all end-use product labels:

"Reporting Ecological Incidents:

“To report ecological incidents, including mortality, injury, or harm to plants and animals, call [registrant phone number].”

Within 60-days of the receipt of this letter, submit a cover letter, a completed Application for Registration (EPA form 8570-1) and copies of your amended product labels. For each label, submit two copies, a clean copy and an annotated copy with changes. In order for the application to be processed, include the following statement on the Application for Registration (EPA form 8570-1):

“I certify that this amendment satisfies the requirements of the NMFS Biological Opinion for bromoxynil, and no other changes have been made to the labeling of this product. I understand that it is a violation of 18 U.S.C. Section 1001 to willfully make any false statement to EPA. I further understand that if this amendment is found not to satisfy the requirements of the NMFS Biological Opinion, this product may be subject to regulatory action.”

Within the required timeframe, submit the required documents to the Re-evaluation section of EPA’s Pesticide Submission Portal (PSP). The PSP can be accessed through EPA’s Central Data Exchange (CDX) using the following link: <https://cdx.epa.gov/>. Please be aware that the Agency is currently not accepting paper submissions because of COVID-19.

Based on the Biological Opinion, in the absence of this revised labeling, bromoxynil products will not have sufficient directions for use and/or precautionary statements to adequately protect federally-listed Pacific salmonid species. Therefore, failure to submit amended labels implementing the NMFS Biological Opinion for bromoxynil within the timeframe above may result in regulatory action.

Please contact Tiffany Green if you have any questions about this letter or the NMFS Biological Opinion. She may be reached at (703) 347-0314 or at green.tiffany@epa.gov

Sincerely,

A handwritten signature in blue ink, appearing to read "Kevin Costello".

Kevin Costello
Branch Chief
Risk Management and Implementation
Branch II
Pesticide Re-evaluation Division

cc: Emily Schmid, PM 25 Registration Division (RD)